The present claimed hard elastic sutures are prepared by methods described in the art such as disclosed in the present specification at page 3 lines 10-36 or by the methods described at page 6 line 18 to 7 line 5 of the present specification. The main features of the manufacturing process are the high stress spinning conditions requiring high melting temperatures and high spin draw ratios. Specifically, polypropylene hard elastic sutures require melt temperatures of 160 to 260°C and spin draw ratios during spinning of 60 to 300.

Listner discloses an isotactic polypropylene monofilament which is spun at a draw ratio of between 1 and 6 in Examples I to XIII. This spin draw ratio is far below the minimum spin draw ratio of 60 mentioned above. At the low spin draw ratios of Listner, the necessary orientation of the crystalline structure of isotactic polypropylene leading to hard elasticity will not occur. Listner then quenches the spun fiber with water, see column 3 lines 39-44 and the Examples. Hard elastic fibers are quenched in air, see U.S. Patent 3,256,258, column 3 lines 53 and 54, and U.S. Patent 3,330,897, column 3 lines 34 and 35, since water quenching is inadequate at the high spin draw ratios of 60 to 300 for polypropylene hard elastic filaments. Copies of the above two U.S. patents are enclosed.

Listner hot stretches (draws) the spun filaments, e.g. to 6.6 times the original length in Example II, column 6, at 285°F. Such hot stretching <u>after</u> spinning removes any hard elastic properties, and is thus not applied in the production of hard elastic filaments. Above U.S. Patent 3,330,897 in column 3 lines 36-41 discloses heating as spun fibers after air-cooling without stretching the yarn during passage through the oven. U.S. Patent

3,256,258 discloses in column 3 lines 55-62 that drawing after spinning is not desirable by stating that preferred products are made without drawing (line 62), and in column 3 lines 63-70 suggests heating to 105 to 106°C in a free-to-shrink condition. The heating step after spinning in above '897 and '258 is also mentioned in the present specification at page 6 lines 8-11. This heating step softens the hard elastic fiber formed to obtain a more flexible material.

Thus, the spinning and other process conditions of Listner are essentially different from those required to obtain hard elastic properties.

The properties of Listner's filaments can be deduced from the stress-strain curve in Fig. 12 of the reference showing properties related to the flexibility, plastic flow and yield stress, as described in column 6 lines 10-47. If the total elongation on the horizontal axis in Fig. 12 is 100%, then point C is at about 8% elongation. As explained in lines 23-27 of column 6, point C indicates the elongation at which the material starts to flow. In other words, on stretching beyond about 8% elongation, the material of the fiber yields and will not spring back at all. This is clearly unlike the hard elastic suture presently claimed which can be stretched to up to 30% elongation on stretching two or more times and will then return to at least about 90% of its original length, in accordance with page 2 lines 29-32 of the present specification. Also, because there is viscoelastic flow after 8% elongation of Listner's filament, this filament will give at that point and the diameter as a result will become smaller. In contrast, the diameter of the present hard elastic suture will be substantially constant on stretching.

Northey describes filaments made from isotactic polypropylene in column 4 lines 58-62. The polypropylene is

first extruded as a filament and then after this spinning step the filament is stretched to several times its original length. This procedure is entirely unlike the procedure for obtaining hard elasticity requiring high stress conditions during spinning. In the absence of such conditions of high temperatures and high draw ratios during spinning, no hard elasticity will develop.

The properties of the Northey filament are also greatly different since the fiber formed has greatly increased strength and reduced elongation. Hard elastic fibers have exactly contrary properties of increased elongation and reduced strength. The best ultimate elongation in Northy is 25% whereas the present sutures have reversible elasticity on at least about 30% elongation after stretching at least once.

Claims 1 to 19 further stand rejected under 35 U.S.C. 103 over Glick 3,565,077. Withdrawal of this rejection is solicited.

Glick is directed to a densified polyglycolic acid sutures. It is not entirely clear why this reference is cited. The present specification contains some comments on the density of the hard elastic sutures, but only in the context of stretching the hard elastic suture. Thus, on stretching the presently claimed sutures, the density of the material reduces resulting in a substantially constant diameter. This is of course not disclosed by Glick. Glick also does not disclose a process to obtain hard elastic sutures. His sutures are spun by conventional methods since there is nothing about the high stress conditions required for hard elasticity. He stretches his monofilaments to obtain higher density (column 5 lines 32-58). This stretching of a conventionally spun fiber will not result in hard elastic properties. Furthermore, column 7 lines 49-58

discloses increase in strength on densification. As noted above, hard elastic fibers generally have <u>less</u> strength than conventional fibers.

In view of the duty of disclosure under 37 CFR §1.56(a), reference is made to U.S. Patent 3,454,011, copy enclosed, disclosing a suture of spandex material which is capable of expanding and contracting with the swelling of the tissue which is sewed together with the spandex suture (column 2, lines 6-9). Of course, the present claims define a suture having hard elastic properties allowing not only to have the suture expand and contract with the sewed tissue but also having the advantage of not changing in diameter while expanding and contracting.

Favorable consideration of the claims and early allowance is respectfully requested.

Respectfully submitted,

Gezina Holtrust

Dated: January 9, 1986

Gezina Holtrust
Attorney for Applicant
Reg. No. 28,222

Pfizer Inc.
235 East 42nd Street
New York, New York 10017
(212) 573-7793

(ES)